

25. A method of establishing a standardized Herbal BioResponse Array (HBR Array) for an herbal composition comprising:

- a) selecting an herbal composition with at least one known BioResponse;
- b) exposing a biosystem to a batch of the herbal composition and collecting data on two or more markers;
- c) storing the marker data of step b) as an HBR Array;
- d) repeating steps b) and c) for one or more additional batches of the herbal composition using two or more of the same or different markers than used in step b);
- e) combining the HBR Arrays obtained in steps c) and d); and
- f) analyzing the combined HBR Array of step e) to generate a standardized HBR Array for the herbal composition, wherein the standardized HBR Array has data for two or more markers that are correlated with at least one known BioResponse of the herbal composition.

26. The method of claim 25, further comprising exposing a biosystem to one or more batches of the herbal composition, collecting data on one or more BioResponses, and adding the collected BioResponse data to the standardized HBR Array for that herbal composition.

27. A method of evaluating an herbal composition comprising comparing marker data generated by exposing a biosystem to the herbal composition to a standardized herbal bioresponse array for the same or substantially the same herbal composition.

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28. A method of evaluating an herbal composition comprising:

- a) exposing a biosystem to a batch of the herbal composition and collecting data on two or more markers;
- b) storing the marker data of step a) as an HBR Array; and
- c) comparing the HBR Array generated in step b) with a standardized HBR Array for the same or a substantially same herbal composition as that of the batch herbal composition.

29. The method of claim 28, further comprising predicting the BioResponse of the batch herbal composition.

30. The method of claim 25 or 28, wherein the markers are selected from the group consisting of molecular, cytogenetic and biochemical markers.

31. The method of claim 25 or 28, wherein the standardized HBR Array further comprises information on plant-related data.

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32. The method of claim 31, wherein the information on plant-related data is selected from one or more of the following: chemical testing, the part of the plant used, the growing conditions of one or more of the individual herbs in the characterized herbal composition, the pre-harvest treatment of one or more of the individual herbs in the herbal composition, the post-harvest treatment of one or more of the individual herbs in the herbal composition, the post-harvest

treatment of the herbal composition, and the relative proportions of the individual herbs in the herbal composition.

33. The method of claim 25 or 28, wherein the BioResponse is selected from the group consisting of physiological responses, morphological responses, cognitive responses, motivational responses and autonomic responses.

34. The method of claim 25 or 28, wherein the biosystem is selected from the group consisting of cells, tissues, organs, whole organisms and *in vitro* assays.

35. A method of predicting the biological activity of an herbal composition comprising exposing a biosystem to the herbal composition, obtaining marker data comprising the biological response of the biosystem to the herbal composition, and comparing the marker data to one or more stored standardized herbal bioresponse arrays of known herbal compositions, wherein the comparison of the marker data to the standardized arrays allows for prediction of the biological activity of the herbal composition.

36. A method for predicting the biological activity of an herbal composition comprising:

- a) exposing a biosystem to a batch of the herbal composition and measuring the differential responses of two or more markers;
- b) storing the marker data of step a) as an Herbal BioResponse Array (HBR Array);

c) comparing the HBR Array of the batch herbal composition to at least one previously-stored standardized HBR Array of a known herbal composition having at least one known biological activity; and

d) predicting the biological activity of the batch herbal composition based on the HBR Array comparison made in step c).

37. The method of claim 36, further comprising repeating steps a) through d) for one or more additional batches of the herbal composition and selecting the batch of the herbal composition that has a desired biological activity.

38. The method of claim 36, wherein additional previously-stored HBR Arrays are used for the HBR Array comparison of step c).

39. The method of claim 36 or 38, wherein the markers are selected from the group consisting of molecular markers, cytogenetic markers and biochemical markers.

40. The method of claim 36 or 38, wherein the previously stored HBR Arrays are standardized HBR Arrays for the same or substantially similar herbal compositions as that of the batch herbal composition.

41. The method of claim 40, further comprising adjusting or modifying the batch herbal composition to produce an HBR Array substantially similar to that of one or more of the standardized HBR Arrays.

42. The method of claim 36 or 38, further comprising using the results of the HBR Array comparison or comparisons to identify specific molecules in the batch herbal composition that have a desired biological activity.

43. The method of claim 36 or 38, further comprising using the results of the HBR Array comparison or comparisons to determine which herbal components of a known herbal composition can be eliminated while maintaining or improving a desired biological activity of the known herbal composition.

44. The method of claim 36 or 38, further comprising using the results of the HBR Array comparison or comparisons to determine whether additional herbal components can be added to a known herbal composition while maintaining or improving a desired biological activity of the known herbal composition.

45. The method of claim 36 or 38, wherein the results of the HBR Array comparison or comparisons identify one or more previously unknown biological activities for the batch herbal composition.

46. The method of claim 36 or 38, further comprising using the predicted biological activity of the batch herbal composition to aid in the design of therapeutics that include both herbal components and synthetic chemical drugs.

47. The method of claims 36 or 38, wherein the biosystem is selected from the group consisting of cells, tissues, organs, whole organisms and *in vitro* assays.

48. A method of determining if an herbal composition meets a standard specification comprising exposing a biosystem to the herbal composition, obtaining marker data comprising the biological response of the biosystem to the herbal composition, and comparing the marker data to one or more stored standardized herbal bioresponse arrays of known herbal compositions, wherein the herbal composition meets the standard specification for marker data that is similar, or is within an acceptable level, to that of the standardized herbal bioresponse arrays.

49. A method of determining if an herbal composition meets a standard specification comprising:

- a) exposing a biosystem to a batch of the herbal composition and collecting data on two or more markers;
- b) storing the marker data of step a) as an Herbal BioResponse Array (HBR Array);
- c) comparing the HBR Array generated in step b) with a standardized HBR Array for the same or a substantially same herbal composition as that of the batch herbal composition; and
- d) determining whether the herbal composition has marker data that is similar, or is within an acceptable level, to that of the standardized HBR Array.

50. The method of claim 49, wherein said determining which herbal compositions have marker data that is similar to that of the standardized HBR Array within an acceptable level is determined quantitatively or qualitatively.

51. The method of claim 49 or 50, wherein the standardized HBR Array includes an acceptable range of variation for each marker.

52. The method of claim 49 or 50, wherein the biosystem is selected from the group consisting of cells, tissues, organs, whole organisms and *in vitro* assays.

53. A method of adjusting the components of an herbal composition so that it meets a standard specification comprising exposing a biosystem to the herbal composition, obtaining marker data comprising the biological response of the biosystem to the herbal composition, comparing the marker data to one or more stored standardized herbal bioresponse arrays of known herbal compositions, and determining whether the herbal composition meets the standard specification by determining if the marker data is similar to, or within an acceptable level of, the data of the standardized herbal bioresponse array, and, if not, adjusting the components of the herbal composition and repeating the process until the marker data of the herbal composition is similar to, or within an acceptable level of, the data of the standardized herbal bioresponse array.

54. A method of adjusting the components of an herbal composition so that it meets a standard specification for the same or substantially the same herbal composition, comprising:

- a) exposing a biosystem to a batch of the herbal composition and collecting data on two or more markers;
- b) storing the marker data of step a) as an Herbal BioResponse Array (HBR Array);

c) comparing the HBR Array generated in step b) with a standardized HBR Array for the same or a substantially same herbal composition as that of the batch herbal composition, wherein the standardized HBR Array also includes an acceptable range of variation for each marker;

d) determining whether the herbal composition has marker data that is within the acceptable level of variation for the standardized HBR Array; and

e) if the marker data is not within the acceptable level of variation for the standardized HBR Array, adjusting the components of the herbal composition.

55. The method of claim 54, wherein steps a) through e) are repeated until the marker data of the herbal composition is within the acceptable level of variation of the standardized HBR Array.

56. The method of claim 54, wherein the biosystem is selected from the group consisting of cells, tissues, organs, whole organisms and *in vitro* assays.

57. A method of adjusting the components of an herbal composition so that it meets the standard specification of a second, different herbal composition comprising exposing a biosystem to the herbal composition, obtaining marker data comprising the biological response of the biosystem to the herbal composition, comparing the marker data to one or more stored standardized herbal bioresponse arrays of the second, different herbal compositions, and determining whether the herbal composition meets the standard specification by determining if the marker data is within an acceptable level of the data of the standardized herbal bioresponse array, and, if not, adjusting



the components of the herbal composition and repeating the process until the marker data of the herbal composition is similar to, or within an acceptable level of, the data of the standardized herbal bioresponse array.

58. A method of changing the components of a first herbal composition so that it meets the standard specification of a second, different herbal composition, comprising:

- a) exposing a biosystem to a batch of the first herbal composition and collecting data on two or more markers;
- b) storing the marker data of step a) as an Herbal BioResponse Array;
- c) comparing the HBR Array generated in step b) with a standardized HBR Array for the second herbal composition, wherein the standardized HBR Array for the second herbal composition also includes an acceptable range of variation for each marker;
- d) determining whether the first herbal composition has marker data that is within the acceptable level of variation for the standardized HBR Array for the second herbal composition; and
- e) if the marker data is not within the acceptable level of variation for the standardized HBR Array for the second herbal composition, changing the components of the herbal composition.

59. The method of claim 58, wherein steps a) through e) are repeated until the marker data of the first herbal composition is within the acceptable level of variation of the standardized HBR Array of the second herbal composition.

60. The method of claim 58 wherein the biosystem is selected from the group consisting of cells, tissues, organs, whole organisms and *in vitro* assays.

61. A method of obtaining a set of discriminating molecular markers for an herbal composition comprising exposing a biosystem to the herbal composition, obtaining a gene expression profile and selecting those markers that are indicative of a bioresponse to the herbal composition.

62. The method of claim 61 further comprising exposing the biosystem to a different batch of the same herbal composition, obtaining a gene expression profile and selecting markers to add to the set of markers and/or delete from the set of markers so as to improve the discriminating power of the set of markers.

63. The method of claim 61 further comprising exposing the biosystem to an herbal composition that is different than the herbal composition used in claim 61, obtaining a gene expression profile and selecting markers to add to the set of markers and/or delete from the set of markers so as to improve the discriminating power of the set of markers.

64. A method of predicting a biological activity of an herbal composition comprising correlating its gene expression profile obtained in claim 61 with a known function of a gene in the profile.

65. A method of establishing a standardized herbal bioresponse array for an herbal composition with a known biological activity comprising exposing a biosystem to the herbal composition, collecting data on changes in gene expression, and storing the data as the standardized herbal bioresponse array.

66. A method of establishing a standardized Herbal BioResponse Array (HBR Array) for an herbal composition with a known BioResponse comprising:

- a) exposing a biosystem to a batch of the herbal composition and measuring the changes in gene expression;
- b) storing the changes in gene expression as an HBR Array;
- c) repeating steps a) and b) using different batches of the herbal composition to generate data for additional HBR Arrays; and
- d) selecting a set of discriminating genetic markers by analyzing the HBR Arrays obtained in step a), b) and c) to establish a standardized HBR Array for the herbal composition.

67. The method of claim 66, wherein the BioResponse is selected from the group consisting of physiological responses, morphological responses, cognitive responses, motivational responses and autonomic responses.

68. A method of evaluating an herbal composition comprising comparing data comprising changes in gene expression generated by exposing a biosystem to the herbal composition to a standardized herbal bioresponse array for the same or substantially the same herbal composition.

69. A method of evaluating an herbal composition comprising:

- a) exposing a biosystem to a batch of the herbal composition and measuring the changes in gene expression;
- b) storing the changes in gene expression as an Herbal BioResponse Array (HBR Array); and
- c) comparing the HBR Array obtained in steps a) and b) with a standardized HBR Array for a substantially equivalent herbal composition.

70. The method of claim 61, 66 or 69, wherein the gene expression takes place transcriptionally.

71. The method of claim 61, 66 or 69, wherein the gene expression takes place translationally.

72. The method of claim 61, 66 or 69, wherein qualitative changes in gene expression are measured.

73. The method of claim 61, 66 or 69, wherein quantitative changes in gene expression are measured.

74. The method of claim 61, 66 or 69, wherein qualitative and quantitative changes in gene expression are measured.

75. The method of claim 61, 66 or 69, wherein the biosystem is selected from the group consisting of cells, tissues, organs, whole organisms and *in vitro* assays.

76. A system for predicting the biological activity of an herbal composition comprising:

- a) a biosystem comprising one or more different types of cells, tissues, and organs or *in vitro* assays;
- b) a batch herbal composition;
- c) a means for exposing the biosystem to the batch herbal composition and measuring the differential responses of selected markers;
- d) a computer processor, including memory, for analyzing and storing the differential response measurements of the selected markers so as to create an Herbal BioResponse Array (HBR Array) data set for the batch herbal composition; and
- e) a computer processor, including memory, for comparing the HBR Array of the batch herbal composition to one or more previously-stored HBR Arrays so as to predict the biological activity of the batch herbal composition, wherein the biological activities of the herbal compositions used to generate the one or more previously-stored standardized HBR Arrays are known.